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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,751	06/20/2003	Randy K. Bledsoe	PU4803USw	5089
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GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 07/28/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/600,751	Applicant(s) BLEDSOE ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 38-43 are pending in the application.
- [2]** Applicant's amendment to claims, filed on 5/8/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims. Claim 38 has been amended relative to the claim set filed on 8/7/07. The amendment appears to correct the informality noted in the Office communication mailed on 4/11/08.
- [3]** Applicant's arguments filed on 5/8/08 in response to the Office action mailed on 11/21/07 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

- [5]** The rejection of claims 38-43 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "identifying in an assay for GR-mediated activity a modeled ligand" and in the recitation of the indefinite article "a" in the phrase "a modeled ligand" in claim 38(c) is withdrawn in view of the instant claim amendment.

Claim Rejections - 35 USC § 103

[6] The rejection of claims 38-43 under 35 U.S.C. 103(a) as being unpatentable over Apolito in view of *In re Gulack* and *In re Ngai* is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 8 beginning at p. 4 of the 11/21/07 Office action.

[7] The rejection of claims 38-42 under 35 U.S.C. 103(a) as being unpatentable over Gillner in view of Högger, *In re Gulack*, and *In re Ngai* is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 9 beginning at p. 6 of the 11/21/07 Office action.

[8] The rejection of claim 43 under 35 U.S.C. 103(a) as being unpatentable over Gillner in view of Högger, *In re Gulack*, and *In re Ngai* as applied to claims 38-42 above, and further in view of Jones is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 10 beginning at p. 8 of the 11/21/07 Office action.

RESPONSE TO ARGUMENT: Beginning at p. 3, bottom of the instant remarks, applicant argues:

The rejection hinges on the construction of the scope of claims 38-43. The Examiner argues that the atomic coordinates recited in claims 38-43 constitute non-functional descriptive matter, and that these atomic coordinates should therefore not be considered in construing the scope of the claims. The Examiner argues that when the limitation of the recited atomic are not considered, claims 38-43 are obvious in view of the cited references. According to the Office Action, the structural coordinates of Table 2 are non-functional because they do not have a functional relationship with the computer on which they are stored. The Examiner states that, "[d]ata, which are fed into a known algorithm whose purpose is to compare or modify those data uses a series of processing steps, do not impose a change in the processing steps and are thus

Art Unit: 1656

nonfunctional descriptive material." (November 21, 2007 Office Action, page 5.) Thus, according to the Office Action, there is a per se rule that data stored in a computer is considered to be non-functional if the data does not affect how the computer performs its function. (November 21, 2007 Office Action, page 10).

However, the relevant case law does not support a finding that the atomic coordinates recited in claims 38-43 are non-functional descriptive matter. In *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller*--to size or to type of substrate, or conveying information about substrate--is not required. What is required is the existence of differences between the appealed claims and the prior art sufficient to establish patentability the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.

Id. at 1386. In the present case, claims 38-43 are directed to methods of using of using structural information about a novel GR expanded binding pocket in the design of GR modulators that fit spatially into this novel pocket, and then testing these modeled ligands in an assay to determine if they modulate the activity of a GR polypeptide. The atomic coordinates recited in the claim 38 are integral to the step of modeling a ligand that fits spatially into the expanded binding pocket. If a different set of atomic coordinates were used in the claimed method, the result of the method would differ from the result achieved in the method recited in claim 38. Thus the atomic coordinates recited in claim 38-43 functionally affect the process of modeling a ligand to fit within the expanded binding pocket. Accordingly, the atomic coordinates are functionally related to the claimed method and this limitation should be considered when construing the scope of these claims. The Examiner has not produced any evidence that the expanded binding pocket described by the recited atomic coordinates would be obvious in view of the prior art references. Accordingly, claims 38-43 recite differences over the prior art that are sufficient to establish patentability, thereby meeting the standard for non-obviousness set forth in *Gulack*.

Furthermore, the atomic coordinates recited in claims 38-43 of the present case are readily distinguishable over the type of descriptive matter at issue in *In re Ngai*, 367 F.3d 1136 (Fed Cir. 2004). In *Ngai*, the issue before the Federal Circuit was whether an inventor could patent a kit composition, where the only difference between the prior art and the claimed kit was the content of instructions included in the kit. The court found that the instructions did not depend on the kit, and the kit did not depend on the instructions; therefore, the addition of the instructions did not make the kit patentable. Thus in *Ngai*, the descriptive material at issue in the rejected claims was only different from the prior art in that it taught "a new use for an existing product." *Id.* At 1339. In

Art Unit: 1656

contrast, the claims 38-43 of the present application are directed to methods of use for a new product, i.e. a novel and non-obvious GR polypeptide expanded binding pocket structure, which can be used, for example, to model ligands that fit spatially into this pocket.

In *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994), the Federal Circuit considered whether a claim limitation reciting attribute data objects (ADOs) stored in memory should be given patentable weight in construing the claim. The court held that the data objects claimed by Lowry were functional because they increased the efficiency of data access and therefore produced a tangible benefit. *Id.* At 1584. However, the court in Lowry did not hold that only those data structures that increased computer efficiency could be considered to produce a tangible benefit. Rather, the increased efficiency of Lowry's data structures was found to be one way in which such tangible benefit could be demonstrated. Similarly, the method recited in claims 38-43 produce a tangible benefit because they allow for the identification of ligands that bind the GR polypeptide expanded binding pocket. Thus, these atomic coordinates are functional related to the claimed method and should be given patentable weight.

In summary, Apolito *et al.*, Gillner *et al.*, and Hogger *et al.*, either alone or in combination, do not teach or suggest all the limitations of claims 38-43 when all the limitations of these claims are properly considered. Therefore, all grounds for rejection under 35 U.S.C. § 103 have been overcome. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Applicant's argument is not found persuasive. According to MPEP 2106.01, "USPTO personnel may not disregard claim limitations comprised of printed matter...However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate". In this case, there appears to be no dispute that with the exception of the structural coordinate data of Table 2, the prior art references combine to teach all claim limitations. Also, there is no dispute that the structural coordinate data of Table 2 is novel or unobvious over the prior art of record. As correctly noted by applicant, the rejection "hinges" on whether or not the structural coordinate data constitute non-

functional descriptive material. The examiner maintains the position that the structure coordinate data of Table 2 is non-functional descriptive material.

According to *Gulack*, “[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight...[T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.” See also MPEP 2112.01.III. As noted in prior Office actions, the recited structural coordinate data appear to be stored on a computer, intended merely as input for a known computer algorithm that, in combination with the elements of the computer, generates a three-dimensional protein structure. In this case, the computer would appear to function in the same manner regardless of whether or not the structural coordinate data were stored on the computer. In other words, the data do not appear to affect how the computer performs or functions. See Cases 6 and 7 of “Annex 3: Comments of the USPTO” of the “Trilateral Project WM4, Comparative studies in new technologies (biotechnology, business methods, etc.), Report on comparative study on protein 3-dimensional (3-D) structure related claims”, Vienna, Austria November 4-8, 2002, pp. 69-76.

According to MPEP 2106.01, “‘functional descriptive material’ consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of ‘data structure’ is ‘a physical or logical relationship among data elements, designed to support specific data manipulation

Art Unit: 1656

functions” (emphasis added) and that “Nonfunctional descriptive material’ includes but is not limited to music, literary works, and a compilation or mere arrangement of data”. In this case, the method involves using a computer and a known algorithm (see, e.g., pp. 83-85 of the specification) to transform the data into a 3-D macromolecular structure. The structural coordinates appear to be an arrangement of data and do not appear to affect how the computer performs or functions and the computer would appear to function in the same way regardless of whether or not the data is stored in a computer’s machine-readable data storage medium, in the same way as music or a literary work stored on a computer would not affect its function. Although applicant asserts the result of the method is dependent upon the atomic coordinates of Table 2, one of ordinary skill in the art would similarly expect the audio or visual “result” to be dependent on the music or literary work stored on a computer, however, MPEP 2106.01 makes clear that “nonfunctional descriptive material” includes music and literary works.

Contrast the atomic coordinate data with the data structure of *Lowry*, which, according to MPEP 2106.01, when stored on a computer readable medium, increases computer efficiency. As noted above, there is no evidence of record that the recited structural data interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of computer processing. Consequently, for reasons of record and the reasons set forth above, the structural coordinate data of Table 2 has not been accorded patentable weight.

At least for the reasons of record and the reasons set forth above, the examiner maintains the position that the claimed invention, which differs from the prior art by only

Art Unit: 1656

the recitation of non-functional descriptive material, would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[9] Status of the claims:

Claims 38-43 are pending.

Claims 38-43 are rejected.

No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/

Application/Control Number: 10/600,751
Art Unit: 1656

Page 9

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656